

REMARKS

Claims 1-37 are pending in the application. Claims 1-23, 26-34, and 36-37 are withdrawn pursuant to a restriction requirement. Favorable reconsideration in light of the amendments, the new claims, and the remarks which follow is respectfully requested.

I. The Amendments

Claims 24 and 35 are amended to recite that the primer pair has a property wherein the primer pair does not detect or prime a non-ruminant DNA. The amendment is fully supported throughout the Specification, for example, pages 10-11 and Figure 6 and accompanying text.

II. Rejection of Claims 24, 25, and 35 Under 35 U.S.C. § 103(a)

Claims 24, 25, and 35 stand rejected under 35 U.S.C. § 103(a) over Saulle et al (*Animal Sci.* 77, 3398-99 (1999) in view of Lowe et al (*Nuc. Acid Res.*, 18, 1757-61 (1990)).

A. Disclosure of the Specification

First, a review of the disclosure of the Specification is in order. The Specification identifies different primer species having different utilities and provides experimental verification of different utilities. As will be discussed at length below, consideration of the utility of a genus disclosed in the cited references compared to the utility of the claimed species is essential for an obviousness analysis.

The Specification discloses that it is possible to create diverse species of primers that all hybridize and amplify the mitochondrial *ATPase8* gene; however, the primers vary in their utility to cross-react and discriminate between different species. For example, the Specification discloses:

SEQ ID NOS.: 1 and 2: have the utility to prime the *ATPase8* gene from any mammal source, ruminates and non-ruminants; SEQ ID NOS.: 3 and 4: have the

utility to prime the *ATPase8* gene of ruminants but will not prime non-ruminant DNA; SEQ ID NOS.: 9-13: have the utility to prime the *ATPase8* gene of cow but will not prime a DNA of any species other than cow including other ruminants.

Experimental results of the function of these primers are disclosed in Figures 5 and 6 and the accompanying text. Identification of primer pairs having different properties allows the identification of samples containing animal matter as original from non-mammals, mammals, ruminants, or a specific species of ruminant. The claims are directed toward a specific primer species having the utility of amplifying DNA from ruminants while having no reactivity with non-ruminants. SEQ ID NOS.: 3 and 4 are the only primer sequences known to have this utility and are distinct from primers having other utility. The utility of SEQ ID NOS. 3 and 4 is validated by the demonstration of other primer pairs, competent to amplify the mitochondrial *ATPase8* gene, that do not have the same cross-reactivity between different species of animal. That is, the data presented in Figures 5 and 6 of the Specification demonstrate that different primers targeted to the mitochondrial *ATPase8* gene can and do have differing utilities to differentiate between DNA originating from different species of animals.

B. Obviousness Analysis.

Saulle et al discloses the nucleotide sequence of mitochondrial *ATPase8* from Alpine Ibex and Lowe et al is a computer program for the automated generation of primer sequences corresponding to an inputted sequence for use in PCR. The Decision on Appeal states a total of six findings of fact. Applicant's representative has never contested the fact that the combination of Saulle et al and Lowe et al will generate a genus of primers that are reasonably expected to function to amplify Ibex DNA during PCR and similar techniques. However, the claims are not directed toward the genus of primers generated by combining the cited references. The claims are directed toward one specific species. It is the position of the USPTO that "those skilled in the art would have known how to obtain primers from a genetic sequence using the algorithms taught in Lowe or

other similar algorithms.” Appeal Decision, page 4. Such has never been disputed. However, the USPTO has not explained how one could predictably generate primers from one inputted sequence having the property to prime the *ATPase8* gene only from ruminants and not for non-ruminants. It is noted that it has not been definitively determined that the program of Lowe et al will output either of SEQ ID NOS.: 3 and 4; therefore, it is not known if the genus formed by the combination of Saulle et al and Lowe et al includes the species of SEQ ID NOS.: 3 and 4. The Applicants reserve the right to submit a declaration under 37 C.F.R. § 1.132 establishing the actual genus generated by the combination of Saulle et al and Lowe et al.

The Decision on Appeal states “A mere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable.” Appeal Decision, pages 4-5. However, it is well-settled law that the mere disclosure of a genus that does not specifically enumerate the now claimed species does not anticipate or make *prima facie* obvious a species or a sub-genus falling within the scope the disclosed genus. “The fact that a claimed species or subgenus is encompassed by a prior art genus **is not sufficient by itself** to establish a *prima facie* case of obviousness.” *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994); MPEP § 2144.08.

MPEP § 2144.08 makes the following statements regarding evaluation of obviousness of a species when a reference discloses a genus:

A proper obviousness analysis involves a three-step process. First, Office personnel should establish a *prima facie* case of unpatentability considering the factors set out by the Supreme Court in *Graham v. John Deere*. See, e.g., *In re Bell*, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993) (“The PTO bears the burden of establishing a case of *prima facie* obviousness.”); *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993); *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966), requires that to make out a case of obviousness, one must:

(A) determine the scope and contents of the prior art;

(B) ascertain the differences between the prior art and the claims in issue;

(C) determine the level of >ordinary< skill in the pertinent art; and

(D) evaluate any evidence of secondary considerations. . . . Finally, Office personnel should evaluate the totality of the facts and all of the evidence to determine whether they still support a conclusion that the claimed invention would have been obvious to one of ordinary skill in the art at the time the invention was made. *Id.*

The first two items that are in dispute, A and B, referenced by MPEP 2144.08 will be discussed in turn under the descriptive headings below.

A. Scope and Content of the Art

In the case of a prior art reference disclosing a genus, Office personnel should make findings as to:

(A) the structure of the disclosed prior art genus and that of any expressly described species or subgenus within the genus;

(B) any physical or chemical properties and utilities disclosed for the genus, as well as any suggested limitations on the usefulness of the genus, and any problems alleged to be addressed by the genus;

(C) the predictability of the technology; and

(D) the number of species encompassed by the genus taking into consideration all of the variables possible.

MPEP 2144.08. Presumably, the program of Lowe et al outputs a list of primer sequences whose only structural characteristic is a certain primary sequence of bases. The precise sequences that would be outputted by the program of Lowe et al are not known. The MPEP stresses special importance for determining the physical or chemical properties and utilities of the disclosed genus. Here, most of the primers generated by the program of Lowe et al by inputting the *ATPase8* gene sequence of Saulle et al presumably have the physical property and utility

of hybridizing to the *ATPase8* gene and to homologous sequences. This is not, and has never been, disputed by Applicants' representative.

Applicants' representative is not aware of any basis for any other utilities that a person having ordinary skill in the art would attribute to the genus of primers outputted by the program of Lowe et al. The Decision on Appeal states, "The Examiner did not rely upon Lowe as teaching the ability of primers from the *ATPase8* sequence to discriminate between homologous targets. This is taught by Saulle." Appeal Decision, page 7. Applicant's representative is perplexed regarding why a person of skill in the art would recognize certain primers corresponding to the sequence of the Ibex *ATPase8* gene as having any utility other amplifying Ibex DNA and homologous sequences. An examination of the sequence of Saulle et al alone does not give any indication of which of the numerous possible primers belong to the claimed utility group of primers that will prime the DNA of ruminants and not non-ruminants and which of the possible primers belong to other utility groups, for example, primers that prime the *ATPase8* gene originating from any animal or primers that only prime the *ATPase8* gene of a specific species.

None of the six findings of fact on pages 3-4 of the Decision on Appeal are on point regarding why a person skilled in the art would recognize a discrimination utility in any of the primers outputted by Lowe et al and specifically which ones. Finding of fact number 4 only states that the claimed primers are homologous to part of the *ATPase8* gene sequence disclosed by Saulle et al; such is not *prima facie* evidence of obviousness of a specific claimed primer species. Finding of fact number 6 only states that one would know how to "obtain" (presumably how to make) the primers generated by Lowe et al. Again, the fact that a genus has been disclosed is not *prima facie* evidence of obviousness of a claimed species.

It is noted that the USPTO has the burden of proof in stating a *prima facie* case of obviousness under section 103(a). A **required** part of such an analysis is a factual determination of the utilities of a disclosed genus when evaluating the obviousness of individual species members of a genus. A concise factual

statement of the USPTO's position regarding all asserted utilities of the genus disclosed by Saulle et al is respectfully requested in the next Office Action.

The number of species outputted by the program of Lowe et al is expected to be numerous. It is noted that the program of Lowe et al has preference for a GC-type sequence pair at the 3' end of primers outputted there from. Lowe et al, page 1758, column 1, first paragraph. As such, if the claimed primers, which do not have a GC-type sequence pair at their 3' end, are outputted by the program of Lowe et al, they will be given a low ranking and presumably appear far down any outputted list. Again, it is not definitely known if the combination of Saulle et al and Lowe et al will generate either of SEQ ID NOS.: 3 and 4.

The ability of primer to prime a specific target sequence of DNA can be gauged to some degree. However, 100% complementarity between a primer and a target sequence is not need for a priming to be successfully performed. Many well established techniques including site specific mutagenesis depend upon deliberate non-complementarity between a primer and target. Therefore, the extent that any primer pair will or will not prime or amplify a homologous DNA sequences cannot be readily determined without reference to the homologous DNA sequences in question.

B. Difference Between the Art and the Claims

[T]he closest disclosed species or subgenus in the prior art reference should be identified and compared to that claimed. Office personnel **should make explicit findings on the similarities and differences between the closest disclosed prior art species or subgenus of record** and the claimed species or subgenus **including findings relating to similarity of structure, chemical properties and utilities.** In *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1537, 218 USPQ 871, 877 (Fed. Cir. 1983), the Court noted that "the question under 35 U.S.C. § 103 is not whether the differences [between the claimed invention and the prior art] would have been obvious" but "whether the claimed invention *as a whole* would have been obvious."

MPEP 2144.08. This stage of the obviousness analysis requires a final determination of the disclosed or recognized utilities of the disclosed genus. As discussed above, Applicant's representative is perplexed regarding why a person of ordinary skill in the art would recognize within the extensive output of the program of Lowe et al different sets of primers with different discrimination utilities.

If the proper factual finding is that Saulle et al only discloses a utility of affinity for Ibex DNA and homologous DNA, then the difference relating to utility between the genus of Saulle et al and the claims is large. The claims are directed toward a species having a different utility of amplifying only ruminant DNA while having no affinity for homologous, non-ruminant DNA.

C. Summary

By only examining the *ATPase8* gene sequence of Saulle et al, a person having ordinary skill in the art will not be able to attribute any utility to any primer homologous to the target sequence other than the primers' likelihood to prime and amplify that specific target DNA. The competency of a primer pair generated by studying one target sequence to prime only ruminant *ATPase8* sequences and not non-ruminant sequences cannot be judged by examining only the *ATPase8* sequence of Saulle et al. As such, there is no motivation for a person having ordinary skill in the art to select the claimed primer pair from a larger genus of primers.

Therefore, it is respectfully requested that the rejection of claims 24, 25, and 35 under 35 U.S.C. § 103(a) be withdrawn.

In the event any fees are due in connection with this document, the Commissioner is authorized to charge those fees to Deposit Account No. 50-1063.

Should the Examiner believe a telephone interview would be helpful to expedite favorable prosecution, the Examiner is invited to contact applicant's undersigned representative at the telephone number listed below.

Respectfully submitted,
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